4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0895]

Issuance of Priority Review Voucher; Material Threat Medical Countermeasure Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a material threat medical countermeasure (MCM) product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that INMAZEB (atoltivimab, maftivimab, and odesivimab-ebgn), manufactured by Regeneron Pharmaceuticals, Inc., meets the criteria for a material threat MCM priority review voucher.

FOR FURTHER INFORMATION CONTACT: Elizabeth Sadove, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-8515, Fax: 301-796-8615, email: EUA.OCET@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a material threat MCM priority review voucher to the sponsor of an approved material threat MCM product application. Under section 565A of the FD&C Act (21 U.S.C. 360bbb-4a), which was added by the Cures Act (Pub. L. 114-255), FDA will award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria upon approval of those applications. FDA has determined that INMAZEB (atoltivimab, maftivimab, and odesivimab-ebgn), manufactured by Regeneron Pharmaceuticals, Inc., meets the criteria for a

material threat MCM priority review voucher. INMAZEB was approved on October 14, 2020. mINMAZEB is a mixture of three monoclonal antibodies indicated for the treatment of infection caused by *Zaire ebolavirus* (Ebola virus) in adult and pediatric patients.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation. For further information about INMAZEB (atoltivimab, maftivimab, and odesivimab-ebgn), go to the Drugs@FDA website at https://www.accessdata.fda.gov/scripts/cder/daf/.

Dated: April 26, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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